

IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

IN RE: DIET DRUGS (PHENTERMINE/)
FENFLURAMINE/DEXFENFLURAMINE)) MDL NO. 1203
PRODUCTS LIABILITY LITIGATION)

THIS DOCUMENT RELATES TO:)
SHEILA BROWN, et al.) CIVIL ACTION NO. 99-20593
v.)
AMERICAN HOME PRODUCTS) 2:16 MD 1203
CORPORATION)

MEMORANDUM IN SUPPORT OF SEPARATE PRETRIAL ORDER NO. 8407

Bartle, C.J.

March 3, 2010

Kevin Elder ("Mr. Elder" or "claimant"), a class member under the Diet Drug Nationwide Class Action Settlement Agreement ("Settlement Agreement") with Wyeth,¹ seeks benefits from the AHP Settlement Trust ("Trust").² Based on the record developed in the show cause process, we must determine whether claimant has demonstrated a reasonable medical basis to support his claim for Matrix Compensation Benefits ("Matrix Benefits").³

1. Prior to March 11, 2002, Wyeth was known as American Home Products Corporation.

2. Jean Elder, Mr. Elder's spouse, also has submitted a derivative claim for benefits.

3. Matrix Benefits are paid according to two benefit matrices (Matrix "A" and Matrix "B"), which generally classify claimants for compensation purposes based upon the severity of their medical conditions, their ages when they are diagnosed, and the (continued...)

To seek Matrix Benefits, a claimant must first submit a completed Green Form to the Trust. The Green Form consists of three parts. The claimant or the claimant's representative completes Part I of the Green Form. Part II is completed by the claimant's attesting physician, who must answer a series of questions concerning the claimant's medical condition that correlate to the Matrix criteria set forth in the Settlement Agreement. Finally, claimant's attorney must complete Part III if claimant is represented.

In February, 2002, claimant submitted a completed Green Form to the Trust signed by his attesting physician, Thomas S. Davidson, M.D. Based on an echocardiogram dated November 20, 2001, Dr. Davidson attested in Part II of Mr. Elder's Green Form that he suffered from moderate mitral regurgitation and an abnormal left atrial dimension.⁴ Based on such findings,

3. (...continued)
presence of other medical conditions that also may have caused or contributed to a claimant's valvular heart disease ("VHD"). See Settlement Agreement §§ IV.B.2.b. & IV.B.2.d.(1)-(2). Matrix A-1 describes the compensation available to Diet Drug Recipients with serious VHD who took the drugs for 61 days or longer and who did not have any of the alternative causes of VHD that made the B matrices applicable. In contrast, Matrix B-1 outlines the compensation available to Diet Drug Recipients with serious VHD who were registered as having only mild mitral regurgitation by the close of the Screening Period or who took the drugs for 60 days or less or who had factors that would make it difficult for them to prove that their VHD was caused solely by the use of these diet drugs.

4. Dr. Davidson also attested that Mr. Elder suffered from New York Heart Association Functional Class I symptoms. This condition, however, is not at issue in this claim.

claimant would be entitled to Matrix A-1, Level II benefits in the amount of \$551,721.⁵

In the report of claimant's echocardiogram, the reviewing cardiologist, Charles F. Dahl, M.D., F.A.C.C., F.A.C.P., stated that claimant had moderate mitral regurgitation with an RJA/LAA ratio of 22%. Under the definition set forth in the Settlement Agreement, moderate or greater mitral regurgitation is present where the Regurgitant Jet Area ("RJA") in any apical view is equal to or greater than 20% of the Left Atrial Area ("LAA").

See Settlement Agreement § I.22.

In October, 2002, the Trust advised Mr. Elder that his claim was selected for audit.⁶ In response, claimant submitted a letter from Dr. Davidson dated October 30, 2002. Dr. Davidson

5. Under the Settlement Agreement, a claimant is entitled to Level II benefits for damage to the mitral valve if he or she is diagnosed with moderate or severe mitral regurgitation and one of five complicating factors delineated in the Settlement Agreement. See Settlement Agreement § IV.B.2.c.(2)(b). As the Trust did not contest the attesting physician's finding of an abnormal left atrial dimension, which is among the complicating factors needed to qualify for a Level II claim, the only issue is Mr. Elder's level of mitral regurgitation.

6. Under the Settlement Agreement, Wyeth and the Trust each designated for audit a certain number of claims for Matrix Benefits and identified the condition(s) to be reviewed during the audit. See Settlement Agreement §§ VI.E. & VI.F.; Pretrial Order ("PTO") No. 2457 (May 31, 2002), Policies and Procedures Order for Audit and Disposition of Matrix Compensation Claims in Audit ("Audit Policies and Procedures") § III.B. Here, Wyeth identified for audit only claimant's level of mitral regurgitation. In PTO No. 2662 (Nov. 26, 2002), we ordered the Trust to audit every claim submitted for Matrix Benefits. The present claim was designated for audit prior to the court's issuance of PTO No. 2662.

stated that, upon review of the echocardiogram, he "found the mitral regurgitation area to be 5.63. The left atrial area was 21.77. The percentage was 25.8 and is consistent with moderate mitral regurgitation." Claimant also submitted an "Echocardiographic Overview" prepared by Amjad Iqbal, M.D. In the Echocardiographic Overview, Dr. Iqbal confirmed that the echocardiogram demonstrated moderate mitral regurgitation and stated that "the left atrial area is greater than 20% but less than 40%."

In December, 2002, the Trust forwarded the claim for review by Ioannis P. Panidis, M.D., F.A.C.C., one of its auditing cardiologists. In audit, Dr. Panidis concluded that claimant had mild mitral regurgitation and that there was no reasonable medical basis for Dr. Davidson's finding that claimant had moderate mitral regurgitation. In support of this conclusion, Dr. Panidis explained that there was an "[o]verestimation of [the] mitral regurgitation area tracing and measurement."

Based on the auditing cardiologist's determination that claimant had only mild mitral regurgitation, the Trust issued a post-audit determination denying Mr. Elder's claim. Pursuant to the Audit Policies and Procedures, claimant contested this adverse determination and requested that the claim proceed to the show cause process established in the Settlement Agreement. See Settlement Agreement § VI.E.7.; PTO No. 2457, Audit Policies and

Procedures § IV.C.⁷ The Trust then applied to the court for issuance of an Order to show cause why Mr. Elder's claim should be paid. On March 21, 2003, we issued an Order to show cause and referred the matter to the Special Master for further proceedings. See PTO No. 2798 (Mar. 21, 2003).

Once the matter was referred to the Special Master, the Trust submitted its statement of the case and supporting documentation. Claimant then served a response upon the Special Master. The Trust submitted a reply on June 9, 2003 and claimant submitted a sur-reply on January 7, 2005. Under the Audit Policies and Procedures, it is within the Special Master's discretion to appoint a Technical Advisor⁸ to review claims after the Trust and claimant have had the opportunity to develop the Show Cause Record. See Audit Policies and Procedures § VI.J. The Special Master assigned a Technical Advisor, Gary J. Vigilante, M.D., F.A.C.C., to review the documents submitted by

7. Claims placed into audit on or before December 1, 2002 are governed by the Audit Policies and Procedures, as approved in PTO No. 2457. Claims placed into audit after December 1, 2002 are governed by the Rules for the Audit of Matrix Compensation Claims, as approved in PTO No. 2807 (Mar. 26, 2003). There is no dispute that the Audit Policies and Procedures contained in PTO No. 2457 apply to Mr. Elder's claim.

8. A "[Technical] [A]dvisor's role is to act as a sounding board for the judge-helping the jurist to educate himself in the jargon and theory disclosed by the testimony and to think through the critical technical problems." Reilly v. U.S., 863 F.2d 149, 158 (1st Cir. 1988). In cases, such as here, where there are conflicting expert opinions, a court may seek the assistance of the Technical Advisor to reconcile such opinions. The use of a Technical Advisor to "reconcil[e] the testimony of at least two outstanding experts who take opposite positions" is proper. Id.

the Trust and claimant and to prepare a report for the court. The Show Cause Record and Technical Advisor Report are now before the court for final determination. See id. § VI.O.

The issue presented for resolution of this claim is whether claimant has met his burden in proving that there is a reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation. See id. § VI.D. Ultimately, if we determine that there is no reasonable medical basis for the answer in claimant's Green Form that is at issue, we must affirm the Trust's determination and may grant such other relief as deemed appropriate. See id. § VI.Q. If, on the other hand, we determine that there is a reasonable medical basis for the answer, we must enter an Order directing the Trust to pay the claim in accordance with the Settlement Agreement. See id.

In support of his claim, Mr. Elder submitted declarations prepared by Dr. Davidson and Dr. Iqbal. In his declaration, Dr. Davidson confirmed the findings set forth in his October 30, 2002 letter. Dr. Iqbal stated in his declaration that: (1) claimant had moderate mitral regurgitation; (2) there was a reasonable medical basis for Dr. Davidson's attestations in claimant's Green Form; and (3) he disagreed with the auditing cardiologist's conclusions.⁹ Claimant also argues that he has established a reasonable medical basis for his claim through his "detailed evidence." According to claimant, the phrase

9. The declaration mistakenly states that another claimant, Shelley Murphy, has moderate mitral regurgitation.

"reasonable medical basis" is a fluid term, which incorporates inter-reader variability and allows for variations and disagreement between physicians.¹⁰ Claimant also asserts that: (1) the auditing cardiologist's attestation form, worksheet and certification are incomplete and, thus, do not comply with the Audit Policies and Procedures; (2) the auditing cardiologist's opinion is inadmissible ipse dixit¹¹ because it fails to explain the lack of a reasonable medical basis; and (3) the Trust's conduct amounts to a violation of claimant's due process rights because he is being wrongfully deprived of Matrix Benefits without the opportunity to be heard in a meaningful manner.

In response, the Trust disputes claimant's characterization of the reasonable medical basis standard as well as claimant's argument that the auditing cardiologist did not follow the Audit Policies and Procedures. The Trust avers that the auditing cardiologist properly completed the attestation form, which incorporates the requirements of the Settlement Agreement and the Audit Policies and Procedures. The Trust further asserts that claimant's inter-reader variability argument

10. In support, claimant submitted a partial transcript of testimony from John Dent, M.D., the Trust's expert during the September, 2002 hearings, which ultimately resulted in the court's issuance of PTO No. 2640 (Nov. 14, 2002). Claimant also submitted a declaration by Jose Rivera, M.D., F.A.C.C., and a transcript of his deposition testimony about three other claimants.

11. Ipse dixit is Latin for "he himself said it." It stands for the proposition that something is asserted but not proved. Black's Law Dictionary 847 (8th ed. 2004).

does not refute the auditing cardiologist's conclusions.

Finally, the Trust contends that claimant's due process arguments must fail because the Audit Policies and Procedures provide adequate notice and an opportunity to be heard.

In his sur-reply, claimant identified several frames from his echocardiogram that he suggests support his argument that there is a reasonable medical basis for the attesting physician's representation that Mr. Elder suffered from moderate mitral regurgitation.

The Technical Advisor, Dr. Vigilante, reviewed claimant's echocardiogram and concluded that there was no reasonable medical basis for the attesting physician's finding of moderate mitral regurgitation. Specifically, Dr. Vigilante stated that:

Only trace mitral regurgitation was noted in the parasternal long axis view and in the apical two chamber view. The mitral regurgitation jet was most impressively seen in the apical four chamber view. This jet traveled towards the lateral portion of the left atrium. However, this jet was mild in severity. The RJA/LAA ratio was less than 15%. The RJA and LAA tracings demonstrated on the tape by the sonographer were inaccurate. The RJA traced area included non-mitral regurgitation jet flow and the LAA traced area was inaccurately small.

. . . Even taking into consideration the issue of inter-reader variability, it would not be possible for a reasonable echocardiographer to conclude that any more significant mitral regurgitation than mild was present on this echocardiogram.

In response to the Technical Advisor Report, claimant argues that: (1) the Technical Advisor improperly substituted

his opinion for the conclusions of the attesting physician; (2) the Technical Advisor failed to apply the appropriate reasonable medical basis standard; and (3) the Technical Advisor's opinion is ipse dixit expert testimony because there was insufficient rationale for his conclusions.

After reviewing the entire Show Cause Record, we find claimant's arguments are without merit. First, we disagree with claimant that the auditing cardiologist's and Technical Advisor's conclusions are unsupported. To the contrary, Dr. Panidis, the auditing cardiologist, specifically explained that claimant did not have moderate mitral regurgitation and that there was an "[o]verestimation of [the] mitral regurgitation area tracing and measurement."¹² Dr. Vigilante also explained that the most impressive regurgitant jet demonstrated an RJA/LAA ratio of only 15% and that "[t]he RJA and LAA tracings demonstrated on the tape by the sonographer were inaccurate." These findings are more than sufficient to support the conclusions of Dr. Panidis and Dr. Vigilante that there was no reasonable medical basis for the attesting physician's representation that claimant had moderate mitral regurgitation.¹³

12. We also disagree with claimant that Dr. Panidis did not adequately complete the Attestation of Auditing Cardiologist, Auditing Cardiologist Worksheet, and Certification of Auditing Cardiologist.

13. For this reason as well, we reject claimant's argument that the conclusions by Dr. Panidis and Dr. Vigilante constitute ipse dixit and that Dr. Vigilante purportedly substituted his opinion for that of the attesting physician.

We also disagree with claimant's characterization of the reasonable medical basis standard. We are required to apply the standards delineated in the Settlement Agreement and the Audit Policies and Procedures. The context of these two documents leads us to interpret the "reasonable medical basis" standard as more stringent than claimant contends, and one that must be applied on a case-by-case basis. For example, as we previously explained in PTO No. 2640, conduct "beyond the bounds of medical reason" can include: (1) failing to review multiple loops and still frames; (2) failing to have a Board Certified Cardiologist properly supervise and interpret the echocardiogram; (3) failing to examine the regurgitant jet throughout a portion of systole; (4) over-manipulating echocardiogram settings; (5) setting a low Nyquist limit; (6) characterizing "artifacts," "phantom jets," "backflow" and other low velocity flow as mitral regurgitation; (7) failing to take a claimant's medical history; and (8) overtracing the amount of a claimant's regurgitation.

See PTO No. 2640 at 9-13, 15, 21-22, 26. Here, Dr. Panidis determined that there was an "[o]verestimation of [the] mitral regurgitation area tracing and measurement" and Dr. Vigilante explained that "[t]he RJA and LAA tracings demonstrated on the tape by the sonographer were inaccurate." Such unacceptable practices cannot provide a reasonable medical basis for the resulting diagnosis and Green Form answer.

Further, claimant's argument that inter-reader variability accounts for the discrepancy between the measurements

of his physicians and those of Dr. Vigilante must fail. As we previously stated, "[b]ased on the Singh grading system, the Settlement Agreement provides the basis for determining a claimant's level of mitral regurgitation. The concept of inter-reader variability is encompassed in this standard." PTO No. 6824 at 10 (Dec. 29, 2006). In this instance, the attesting physician's opinion cannot be medically reasonable where the Technical Advisor concluded that claimant's echocardiogram demonstrates an RJA/LAA ratio of at most 15%. Adopting claimant's argument on inter-reader variability would expand the range of moderate mitral regurgitation and would allow a claimant to recover Matrix Benefits when his or her level of mitral regurgitation is below the threshold established by the Settlement Agreement. This result would render meaningless this critical provision of the Settlement Agreement.

Finally, claimant's argument that the Trust deprived him of due process is without merit. It is claimant's burden in the show cause process to show why he is entitled to Matrix Benefits. See Audit Policies and Procedures § VI.D. The Audit Policies and Procedures, as approved by this court, comply with due process requirements, as claimant has had notice and an opportunity to present his evidence in support of his claim.

For the foregoing reasons, we conclude that claimant has not met his burden in proving that there is a reasonable medical basis for finding that he had moderate mitral regurgitation. Therefore, we will affirm the Trust's denial of

Mr. Elder's claim for Matrix benefits and the related derivative
claim submitted by his spouse.